

Remarks

Entry of the foregoing amendments and the following remarks are respectfully requested.

A new corrected page 27 of the specification previously presented in Response dated May 1, 2008 is submitted per Examiner's request. The added text has been underlined.

Claim 76 has been amended and is now drawn to the method of claim 75 on which it depends.

Entry of amendments to the specification and claims is respectfully requested.

STATUS OF CLAIMS

Claims 4, 9, 39, 42, 46, 49, 52, 57, 62 and 93 are being examined.

Claims 4, 9, 39, 42, 49, 52, 57, 62 and 93 are directed to an allowable product.

Claims 74-76 and 86-87 have been rejoined by Examiner as directed to the process of making or using the allowable product.

Claims 5, 10, 11-38, 43, 45, 47, 48, 53, 58, 63, 65-73, 77-86, 88-90 have been withdrawn by Examiner as being drawn to a nonelected invention.

Claims 1-3, 6-8, 40-41, 44, 50-51, 54-56, 59-61, 64, 86 and 87, 91-92 have been canceled.

The status of claim 46 was not indicated by Examiner. But since claim 46 is dependent on allowed claim 9, Applicants expect it also is allowed. Confirmation of allowance of this claim is respectfully requested.

In re Application of Lanar et al.
Serial no. 10/706,435
November 13, 2008

OBJECTIONS AND REJECTIONS

Examiner has requested a new Oath/Declaration because the corrections to the previously executed Oath/Declaration were not initialed and dated. An executed, corrected Oath/Declaration will be submitted as soon as it is in hand.

The specification stands objected to due to formalities. The submitted page 27 is believed to correct this formality. Withdrawal of the objection is respectfully requested.

Claims 86 and 87 stand rejected under 35 U.S.C. 112, first paragraph as allegedly not enabled. These claims have been canceled. Withdrawal of the rejection is respectfully requested.

Claim 76 stands rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. Amended claim 76 is believed to be definite. Withdrawal of the rejection is respectfully requested.

All objections and rejections have been addressed. This application is believed to be in condition for Allowance and Notice to that effect is respectfully requested. Should the Examiner have a need to discuss the claims or amendments to the claims, Examiner is encouraged to contact Applicants by telephone.

Respectfully submitted,

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By *Sana A. Pratt*
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that effective amounts will be found within a relatively large, non-critical range. An appropriate effective amount can be readily determined using only routine experimentation. Preferred ranges of

5 LSA-NRC for prophylaxis of malaria disease are about 0.01 to 1000 ug/dose, more preferably about 0.1 to 100 ug/dose most preferably about 10-50 ug/dose. Several doses may be needed per individual in order to achieve a sufficient immune response and

10 subsequent protection against malaria.

More particularly, the present invention contemplates essentially purified LSA-NRC and a method for isolating or purifying recombinant LSA-NRC protein.

15 The term 'LSA-NRC' refers to a polypeptide or an analogue thereof (e.g. mimotopes) comprising an amino acid sequence (and/or amino acid analogues) defining at least one LSA-1 epitope. Typically, the sequences defining the epitope correspond to the

20 amino acid sequence of LSA-1 region of *P. falciparum* (either identically, by harmonization, or via substitution of analogues of the native amino acid residue that do not destroy the epitope). The LSA-NRC(H) protein or polypeptide corresponds to a

25 nucleotide sequence identified in SEQ ID NO: ~~22~~²⁵ and an amino acid sequence identified in SEQ ID NO: ~~25~~²⁶ which spans from amino acid 28-154 of the N-terminal region, two 17 aa repeats of the 86 possible from the full length molecule, and the C-terminal region

30 amino acids #1630-1909 of LSA-1 3D7 allele. Upon expression in *E. coli* LSA-NRC(H) is expected to have an approximate molecular weight of 53 kDa as determined by SDS-PAGE.

that effective amounts will be found within a relatively large, non-critical range. An appropriate effective amount can be readily determined using only routine experimentation. Preferred ranges of LSA-NRC for prophylaxis of malaria disease are about 0.01 to 1000 ug/dose, more preferably about 0.1 to 100 ug/dose most preferably about 10-50 ug/dose. Several doses may be needed per individual in order to achieve a sufficient immune response and subsequent protection against malaria.

More particularly, the present invention contemplates essentially purified LSA-NRC and a method for isolating or purifying recombinant LSA-NRC protein.

The term 'LSA-NRC' refers to a polypeptide or an analogue thereof (e.g. mimotopes) comprising an amino acid sequence (and/or amino acid analogues) defining at least one LSA-1 epitope. Typically, the sequences defining the epitope correspond to the amino acid sequence of LSA-1 region of *P. falciparum* (either identically, by harmonization, or via substitution of analogues of the native amino acid residue that do not destroy the epitope). The LSA-NRC(H) protein or polypeptide corresponds to a nucleotide sequence identified in SEQ ID NO:25 and an amino acid sequence identified in SEQ ID NO:26 which spans from amino acid 28-154 of the N-terminal region, two 17 aa repeats of the 86 possible from the full length molecule, and the C-terminal region amino acids #1630-1909 of LSA-1 3D7 allele. Upon expression in *E. coli* LSA-NRC(H) is expected to have an approximate molecular weight of 53 kDa as determined by SDS-PAGE.